GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1632
ANSWERED ON:14.03.2005
PRODUCTION OF QUALITY DRUGS
Chowdhury Shri Adhir Ranjan;Shakya Shri Raghuraj Singh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the details of the specific formats of documentation that have been specified by the Government, which are essential to be maintained for production of quality drugs under good manufacturing practices;

(b) whether in the absence of such guidelines, the field staff of the Government is twisting the rules leading to harassment and closures of many small scale pharma units; and

(c) if so, the steps taken by the Government to remove the practical difficulties of small scale units in this regard?

Answer

THE MINISTER OF CHEMICALS AND FERTILIZERS AND MINISTER OF STEEL (SHRI RAM VILAS PASWAN):

(a) According to the revised Schedule M (Good Manufacturing Practices) and Schedule U of the Drugs & Cosmetics Rules, following documents are to be maintained by the manufacturers:

(i) Master Formula Records;

(ii) Batch Manufacturing Records;

(iii) Records of raw materials;

(iv) Batch Packaging Records;

(v) Records of analysis;

(vi) Site Master File;

(vii) Manufacturing Records relating to manufacture of sterile products;

(viii) In-process records;

(ix) Distribution records;

(x) Standard operating Procedures for different activity.

(b) Under the Drugs and Cosmetics Act, 1940, the responsibility for regulating manufacture and sale of drugs rest with the State Governments.

(c) Does not arise.